

A feasibility study of prescribing chair based pedal exercises for older people admitted to hospital on function and mobility compared to standard care

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| Submission date 21/07/2015 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 27/07/2015 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 07/12/2017 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

The British Heart Foundation recommends physical activity in frail older people. Unfortunately, older patients in hospital spend the majority of their time in a sedentary state. Physical inactivity in hospital leads to poorer health outcomes. Encouraging physical activity in hospital is challenging due to a number of reasons ranging from a limited number of therapists (who usually deliver the exercise sessions), limited therapy time, older patients unable to recall exercises prescribed, lack of patient engagement and motivation; and concern of causing falls. Therefore, chair based pedal exercises offer a simple method of improving physical activity. Its repetitive nature is much easier to follow and this helps those with memory concerns. Resistance training as part of pedal exercise may improve muscle strength. All this should result in improved lower limb function. An activity that involves sitting down is more likely to reassure both patients and staff regarding the risk of falls and resulting injury. Chair based pedal exercise in addition to usual ward care may improve healthcare outcomes. We propose a study to evaluate how feasible it is to deliver regular chair based pedal exercises (the intervention) on older people (≥ 65 years old) admitted to an acute medical ward.

Who can participate?

People aged at least 65 admitted to an acute geriatric ward that are able to co-operate and sit in a chair on their own for at least 10 minutes

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 receive standard care, that is the care currently given on the ward. Those in group 2 receive the intervention. This includes

regular chair based pedal exercises for 5 minutes 3 times a day until they leave hospital or after 7 days, whichever comes. This is in addition to the standard care delivered. Participants are asked to pedal continuously with no pre-specified targets set, e.g. rpm or level of resistance. This exercise is initially supervised by a member of the research team and then supervised by

members of the ward team. This is to replicate 'real life' hospital setting where exercises in hospital are initiated and observed by a therapist and the patients encouraged to continue with the exercises with support by the ward team. Participants in both groups have access to the ward physiotherapist and an inpatient therapy plan as part of their standard care. The participants also have similar access to medical, nursing and other allied healthcare staff.

What are the possible benefits and risks of participating?

Participants offered pedal exercises will be able to maintain their fitness whilst in hospital. Participating in the study will help to provide the research team with information to improve physical activity and mobility in hospital. There are no known side effects. Tiredness due to the pedal exercise is possible. Hence, if a participant suffers with any heart or lung problems, the research team would urge the participant to pace him or herself, to stop if any discomfort arises and inform the healthcare and research team. Participants may also experience mild discomfort from wearing the activity monitor with its associated dressing. If this was the case the monitor could be repositioned.

Where is the study run from?

Queens Medical Centre, Nottingham University Hospitals NHS Trust.

When is study starting and how long is it expected to run for?

October 2014 to October 2016

Who is the main contact?

Dr Terence Ong

Contact information

Type(s)

Scientific

Contact name

Dr Terence Ong

Contact details

Department of Healthcare for Older People, Queens Medical Centre, Derby Road
Nottingham
United Kingdom
NG7 2UH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NUH R&I 14HC024

Study information

Scientific Title

The effect of chair based pedal exercises for older people admitted to an acute hospital on function and mobility compared to standard care: a feasibility study

Acronym

PEDAL

Study objectives

Chair based pedal exercise in addition to standard care improves muscle function in older people admitted to hospital compared to standard care alone

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee West Midlands - Coventry & Warwickshire, ref: 15/WM/0149

Study design

Randomised feasibility trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Muscle strength of older people admitted to hospital

Interventions

There will be 2 treatment groups (standard care and intervention group).

1. Standard care is what is currently done on the ward.
2. The intervention is prescribed regular chair based pedal exercises for 5 minutes 3 times a day until discharge or 7 days, whichever comes first in addition to the standard care delivered. Participants will be asked to pedal continuously with no pre-specified targets set, e.g. rpm or level of resistance. This exercise will be supervised initially by a member of the research team

with subsequent supervision by members of the ward team. This is to replicate 'real life' hospital setting where exercises in hospital are initiated and observed by a therapist and the patients encouraged to continue with the exercises with support by the ward team.

Both arms of the trial will have access to the ward physiotherapist and an inpatient therapy plan as part of their standard care. The participants will also have similar access to medical, nursing and other allied healthcare staff.

Intervention Type

Device

Primary outcome measure

Muscle strength

Secondary outcome measures

1. Changes in mobility (Elderly Mobility Scale)
2. Physical activity (body worn accelerometers)
3. Inpatient falls
4. Discharge destination
5. inpatient and 30 day mortality

Overall study start date

29/10/2014

Completion date

10/10/2016

Eligibility

Key inclusion criteria

1. Older people (≥ 65 years) admitted as an emergency to an acute geriatric ward
2. Able to co-operate and able to sit in a chair independently for a continual period of at least 10 minutes

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

50

Key exclusion criteria

1. Terminally ill or moribund
2. Need for isolation
3. Bed bound prior to admission

4. Predicted length of stay ≤ 48 hours
5. Unable to use the pedal exerciser due to functional impairment, e.g. lower limb fracture, lower limb pain, leg amputation, foot deformity

Date of first enrolment

10/08/2015

Date of final enrolment

01/04/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Queens Medical Centre**

Derby Road

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Research and Innovation, Nottingham University Hospitals NHS Trust

Sponsor details

Queens Medical Centre, Derby Road

Nottingham

England

United Kingdom

NG7 2UH

Sponsor type

Hospital/treatment centre

Website

<http://nuhrise.org/>

ROR

<https://ror.org/05y3qh794>

Funder(s)

Funder type

Not defined

Funder Name

British Geriatrics Society

Alternative Name(s)

BGS

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

High impact conferences and journals.

Intention to publish date

30/04/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Terence Ong, terenceong@doctors.org.uk. Anonymised participant level data will be available for analysis upon request.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| Basic results | | 02/11/2017 | 07/12/2017 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |